DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED

cc: HFI-35/FOI Staff
DWA

December 6, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-15

Kenneth DeMuth
President
Home Healthcare Technologies, Inc.
12970 West Bluemound Road
Elm Grove, Wisconsin 53122

Dear Mr. DeMuth:

During our November 25-26, 1996, inspection of your medical gas manufacturing facility, HME, Division of Home Healthcare Technologies, Inc., located at 212 South Curtis Road, West Allis, WI, our investigator documented serious violations of the Good Manufacturing Practice Regulations (GMP), Title 21, Code of Federal Regulations, Parts 210 and 211. Drugs manufactured in a facility which is not in compliance with GMP are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

GMP deviations observed in your facility include:

- Failure to establish or periodically re-establish the reliability of your supplier's analysis of oxygen. You rely upon the supplier's Certificate of Analysis to assure the identity and purity of liquid oxygen.

- Failure to witness testing by your supplier or, in lieu of this, failure to perform your own tests for purity or identity of incoming liquid oxygen prior to distribution.

- Failure to test the identity of the contents of cryogenic home vessels which have been sent out for repair or maintenance prior to redistribution.

At the close of our inspection, Investigator John P. Hermann discussed these deviations with, and delivered form FDA-483 to, Mr. James D. Cupertino, General Manager, HME, West Allis, WI.

This identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence for each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Lawrence R. Murphy, Food and Drug Administration, Minneapolis District Office, 240 Hennepin Avenue, Minneapolis, MN 55401.

Sincerely

John Feldman
Director
Minneapolis District

LRM/ccl

xc: James D. Cupertino
General Manager
HME, Div. of Home Healthcare Technologies, Inc.
212 South Curtis Road, #214
West Allis, WI 53214